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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/749,907

12/30/2003

Saskia Marc Antoinette Van De Zande

2002.028 US C1

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04/14/2006

INTERVET INC.

PATENT DEPARTMENT

PO BOX 318

MILLSBORO, DE 19966-0318

EXAMINER

CHEN, STACY BROWN

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 04/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/749,907	ANTOINETTE VAN DE ZANDE ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-6,9-11 and 13-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-6,9-11 and 13-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/1/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 1, 2006 has been entered. Claims 1, 4-6, 9-11 and 13-16 are pending and under examination.

Response to Amendment

2. The following objection and rejections are withdrawn:
- The objection to claims 1, 4-6, 9-11 and 13-16 for misspelling of the term, "ECACC", is withdrawn in view of Applicant's amendment.
 - The rejection of claims 1, 4-6, 9-11 and 13-16 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in view of Applicant's amendment.
 - The rejection of claims 1, 4-6, 9-11 and 13-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement with regard to the avian Reovirus ERS deposited at the ECACC under accession no. 99011475, is withdrawn because the incorporation by reference from PCT/US03/31901 is deemed

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proper. The limitation, "of at least 75% in a plaque reduction assay", is also properly incorporated by reference from PCT/US03/31901.

- The rejection of claims 1, 4-6, 9-11 and 13-16 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement because the Reovirus strain deposited at the ECACC under accession number 99011475 did not meet the enablement requirement, is withdrawn in view of Applicant's amendment filed March 1, 2006.

Specification

3. (*New Objection*) The specification is objected to for the following informality:

The amended portion of the specification ("Related Applications"), filed March 1, 2006, contain a typo in the reference to PCT/US03/31901. Correction is required.

Response to Arguments

Claim Rejections - 35 USC § 112

4. The rejection of claims 1, 4-6, 9-11 and 13-16 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of propagating ERS 1037, ERS 060E and ERS 074 in Vero cells without prior adaptation, does not reasonably provide enablement for a method of propagating any avian Reovirus without prior adaptation to Vero cells, is maintained for reasons of record.

Applicant's arguments have been carefully considered but fail to persuade. Applicant's substantive arguments are primarily directed to the following:

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- Applicant argues that the claimed methods are limited to propagating ERS isolates that can multiply on Vero cells to a titer of at least about 3.0 TCID₅₀/ml without prior adaptation, and belong to a defined antigenic class. The antigenic class of ERS isolates is defined in that its members are all able to induce antiserum in an animal, which antiserum causes a reduction of the plaques formed by the avian reovirus ERS sample which is deposited at the ECACC under accession no. 99011475, of at least 75% in a plaque reduction assay. The members of the antigenic class all positively react with polyclonal avian reovirus antiserum but not with monoclonal antibodies identified by accessions nos. 99011472, 99011473 and 99011474. Applicant argues that one skilled in the art would be able to practice the claimed method, as it is routine and does not require undue experimentation.
- Applicant also argues that Drastini and Nwajei support Applicant's invention because they show that not all avian reoviruses are capable of growing on Vero cells without prior adaptation. Applicant argues the fact that they discovered avian reoviruses capable of growing on Vero cells with prior adaptation is surprising. Applicant points to Nibert *et al.* (*Fields Virology*, 2000, 4:1682) for evidence that as of 2001, no chicken infecting reovirus has been shown to grow on Vero cells, without prior adaptation.

In response to Applicant's arguments, the Office recognizes that the claims are drawn to methods that use a specific antigenic class of Reoviruses. It is understood that the skilled artisan has the ability to carry out the claimed method steps. The question that the Office is raising, is whether Applicant has provided enough guidance that one of skill in the art would be able to

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propagate the avian reoviruses having the claimed capabilities. If given the reovirus(es) with all of the claimed properties, the step of propagating a virus that meets all the criteria is well within the ability of the skilled artisan. However, Applicant has only provided three examples of viruses having all of the claimed characteristics. While one would be able to propagate ERS 1037, ERS 060E and ERS 074, one would not be able to find other ERS of the same class without undue experimentation. Recall that the discovery of isolates ERS 1037, ERS 060E and ERS 074 was surprising and unexpected. While Applicant has discovered some of the characteristics of these three strains, there is no guidance on how to find others.

If one of skill in the art were guided by the instant claims and specification, that person would need to test each and every Reovirus for the claimed functions until more are discovered. Only then could the viruses be propagated. Given the unexpectedness of the three strains to grow on Vero cells without prior adaptation, one of skill in the art needs access to strains that have the claimed functions. Access to three such strains has been given, ERS 1037, ERS 060E and ERS 074. If Applicant intends for the skilled artisan to first discover the strains of reovirus that have the claimed characteristics, and then use the discovered viruses in the instant method of propagation, then the claim is considered a reach-through claim that Applicant has not adequately taught how to make. Aside from ERS 1037, ERS 060E and ERS 074, the specification does not enable the highly skilled artisan to practice the full scope of the claims.

5. The rejection of claims 1, 4-6, 9-11 and 13-16 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is maintained for reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way

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as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a method of propagating avian Reovirus that are isolated from poultry and grown to suitable titer on Vero cells, without prior adaptation, comprising the steps of inoculating a Vero cell line with the avian Reovirus, allowing the Reovirus to multiply, and harvesting the avian Reovirus.

Applicant's arguments have been carefully considered but fail to persuade. Applicant argues that the claims as amended recite a specific class of avian Reovirus, thus limiting the scope of the invention to a smaller class of avian Reovirus. The antigenic class of ERS isolates is defined in that its members are all able to induce antiserum in an animal, which antiserum causes a reduction of the plaques formed by the avian reovirus ERS sample which is deposited at the ECACC under accession no. 99011475, of at least 75% in a plaque reduction assay. The members of the antigenic class all positively react with polyclonal avian reovirus antiserum but not with monoclonal antibodies identified by accessions nos. 99011472, 99011473 and 99011474. Applicant argues that there is adequate description in terms of physical and/or chemic properties and functional characteristics. Applicant argues that the specification teaches methods of identifying ERS isolates useful according to the claimed invention, and hence, methods of propagating the isolates.

In response to Applicant's argument, the Office acknowledges that Applicant has characterized three structures (isolates) and their functions. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. So while there is adequate structure, function, and structure/function correlation, there is not adequate possession of how to

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make the claimed product. While one would be able to propagate ERS 1037, ERS 060E and ERS 074, if handed to them, one would not be in possession of the larger genus of methods of making viruses of the antigenic class of reoviruses. Recall that the discovery of isolates ERS 1037, ERS 060E and ERS 074 was surprising and unexpected. In other words, one would have to find other members of the antigenic class based on the three examples provided. Once those members are found, having the appropriate characteristics, one would be able to use the discovered viruses to propagate them.

Given the unexpectedness of the three strains to grow on Vero cells without prior adaptation, one of skill in the art would need more representatives of the genus of the ERS antigenic class. Access to three such strains has been given, ERS 1037, ERS 060E and ERS 074. If Applicant intends for the skilled artisan to first discover the strains of reovirus that have the claimed characteristics, and then use the discovered viruses in the instant method of propagation, then the claim is considered a reach-through claim that is inadequately described. Aside from ERS 1037, ERS 060E and ERS 074, the specification does not describe the invention in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Conclusion

6. No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Stacy B. Chen 4/12/2006
Stacy B. Chen
Primary Examiner
April 12, 2006